

REMARKS

Claim 20 has been cancelled . Newly added claim 26 incorporates the features of claims 4 and 6.

The specification has been amended to correct obvious minor translation errors. See, e.g., ASTM F-136 (attached), which corresponds to ISO 5832-3 and DIN 5832-3. With regards to the correct spelling of the implant alloy, there are national differences. In the United States for example, numbers are customarily placed before the alloying element (i.e., Ti 6Al 4V). In Germany, numbers are customarily placed after the alloying element (i.e., TiAl6V4) . The name of the alloy is not a chemical formula as can be seen at page 4 line 30 of the German priority document (DE10029520). On page 2 of the Office Action the Examiner points to page 11 of WO 92/13984. Both Example #3 and #4 on page 11 of WO 92/13984 (attached) identify the customary US naming for the implant alloy (i.e., Ti 6Al 4V). The specification has been amended to use the name of the alloy in accordance with the conventional German practice.

No new matter has been added.

Claim Rejections – 35 U.S.C. § 102

Applicants' claims 1-3 and 5-6 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4780450, to Sauk et al. ; claims 1-3 and 5-7 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,573,771, to Geistlich et al. and claims 1-3, 5 and 7 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,543,441, to Rhee et al. Applicants respectfully traverse these rejections.

The disclosed compositions of Sauk, Geistlich and Rhee (previously discussed) merely relate to mixtures of components.

Applicants' collagen matrix, which is mineralized with calcium phosphate by precipitating calcium phosphate from a solution in the presence of collagen, has definite physical properties (e.g., permeable structure) which are analogous to the structure of bone produced *in vivo*, and further exhibits good adhesion directly onto metallic implant surfaces. The formation of the coated implant of applicants' claimed invention is based on a biometric process wherein the mineralized collagen is formed under conditions found *in vivo*. In this process, hydroxyapatite is formed by calcium and phosphate ions from an electrolyte solution

transforming from an amorphous phase to a crystalline phase. The resulting hydroxyapatite has a needle-like appearance and is nanocrystalline as in bone. The unique physical characteristics, as examined by electron microscopic, are further discussed in examples 1-4 of the specification.

The mixtures of components taught in Sauk, Geistlich, and Rhee do not teach a collagen matrix mineralized with a calcium phosphate phase wherein the coating is obtained by precipitating calcium phosphate from a solution in the presence of collagen.

Therefore, it is respectfully requested that the rejections under 102 should be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Applicants' Claim 8 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,573,771 to Geistlich et al.; and applicants Claims 1-5 , 7-10 and 21-25 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,543,441 to Rhee et al., in view of U.S. Patent 5,205,921 to Shirkanzadeh et al. and further in view of US 5,776,193 to Kwan et al. Applicants respectfully traverse these rejections.

Kwan et al. teaches a bone grafting matrix. Insoluble fibrillar collagen is homogenized with calcium chloride and tribasic sodium phosphate. To prepare the bone grafting matrix, soluble collagen binder is added to a mineralized collagen slurry, blended, frozen and lyophilized. The calcium phosphate minerals are immobilized on the matrix and comprise particles of average diameter less than about five microns (see col. 5 lines 17-23). Kwan does not disclose a coated implant or a process for coating an implant. Further, Kwan does not teach a coating that is mineralized with a calcium phosphate that has been precipitated from a solution in the presence of collagen.

Shirkanzadah teaches an electrochemical deposition of a bioactive calcium phosphate coating. The electrolyte may further contain collagen. At col.3, lines 46-48 of '921 it is pointed out that the micro pores of the calcium phosphate layer encourage adhesion of macro molecules such as collagen. Thus, the collagen component is not mineralized with a calcium phosphate phase wherein the coating is obtained by precipitating calcium phosphate from a solution in the presence of collagen.

As noted above, the compositions of Geistlich and Rhee are simply mixtures which may contain calcium phosphate and collagen. These compositions differ markedly from a collagen matrix mineralized with a calcium phosphate phase wherein the coating is obtained by precipitating calcium phosphate from a solution in the presence of collagen. Additionally, nowhere in Shirkanzadeh, Geistlich, Kwan or Rhee is there a disclosure or suggestion of an electrochemical process that would arrive at a product of applicant's claimed invention. Therefore, the rejections under section 103 should be withdrawn.

In view of the amendments and above remarks, favorable consideration is courteously requested. However, if there is any remaining issue(s) which can be expeditiously resolved by a telephone conference, the Examiner is courteously requested to telephone the undersigned at the number indicated below.

Respectfully submitted,


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